Docket No. 455-016 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	
JEFFREY S. KIEL ET AL.	Examiner: SHEIKH, HUMERA N.
Serial No.: 10/119,285	Group Art Unit: 1615
Filed: April 9, 2002	

For: PROCESS FOR PREPARING TANNATE LIQUID AND SEMI-SOLID DOSAGE FORMS

DECLARATION UNDER 37 CFR 1.132

1.) My name is Timothy R. Flynn, M.D. I reside in Norcross, Georgia. I have been a physician for 14 years. I practice in the field of Internal Medicine/Endocrinology.

2.) I hold a degree in Medicine conferred by the University of Toronto in Toronto, Ontario. Following medical school, I completed a three-year residency at the University of Toronto and Harvard Medical School Teaching Hospital. Next, I completed an Endocrinology and Metabolism Fellowship at the Harvard Medical School Teaching Hospitals. Presently, I am in private practice.

3.) I am a member of a number of professional organizations including the Endocrine Society. I have received a number of awards, including Lois and K.J.R. Wrightman Award from the University of Toronto and the Henry Christian Award for Excellence in Research from the American Federation for Clinical Research Foundation. My Curriculum Vitae is attached hereto as Exhibit "A."

4.) I have no ownership interest in Kiel Laboratories, Inc., the owner of this patent application, nor have I received any remuneration for giving this Declaration.

5.) Tannate forms or complexes of many active pharmaceutical ingredients including antihistamines, antitussives, decongestants and anticholinergics are presently available for treating various medical conditions. Generally actives in tannate form are released gradually over time and therefore provide prolonged pharmaceutical activity.

6.) Any variation in the active content of the tannate form can potentially alter both the rate and total amount of drug delivered to a patient. Consequently, variability increases the risk of a patient (a) receiving an insufficient dosage to effectively treat an illness or (b) being subjected to adverse side effects as a result of an excessive dosage. When one considers that many of the patients treated with tannate forms of active pharmaceutical ingredients are children with limited ability to metabolize a drug, it is easy to appreciate that uniformity of active ingredient content is a critically important consideration in treatment selection.

7.) At present, the FDA and other international regulating entities consider variations of only a few percent in the amount of active ingredient contained in a pharmaceutical product to be potentially dangerous. Currently, however, the tannate forms of well known active pharmaceutical ingredients such as antihistamines, antitussives, decongestants and anticholinergics are not required to be approved by the FDA and, as such,

are not subjected to content verification by this regulatory agency. In view of this fact, as a responsible physician I consider it critically important to the health of my patients to utilize tannate forms of active pharmaceutical ingredients produced in accordance with methods that best insure content uniformity.

8.) It is my understanding that tannate salt forms of active pharmaceutical ingredients including antihistamines, antitussives, decongestants and anticholinergics made by Kiel Laboratories, Inc. in accordance with the process claimed in U.S. patent application serial no. 10/199,285 are characterized by greater active content uniformity than such products made by the process set forth in U.S. Patent 5,663,415 to Chopdekar et al. As such, it is my opinion as a responsible physician that tannate salt forms of active pharmaceutical ingredients made in accordance with the process claimed in U.S. patent application serial no. 10/119,285 are superior to similar products made by the process set forth in U.S. Patent 5,663,415 and as such represent a significant advance in the art. More specifically, the products of the process of U.S. patent application serial no. 10/119,285 allow one to better treat a patient with the desired amount of active ingredient at the desired rate of release while minimizing the risk of subjecting the patient to potential adverse side effects due to inadvertent overdosing.

The undersigned further declares that all statements made herein of his own knowledge are true and that all statements made on information and

belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

TIMOTHY R. FLYNN, M.D.

4/1/2004
DATE